

Supplier Response to Corrective Action Request (CAR)

Suppliers should use the following guidelines when answering CARs (refer to CAR form below on pg 2):

For all variances recorded on CAR's, containment, root cause analysis and effective corrective action are mandatory requirements. This corrective action must be in sufficient detail to prevent recurrence of reported variance or noncompliance.

The Corrective Action Response shall be structured using the following steps as a guide to achieve effective product and systems integrity.

Containment - Assure that all suspect product has been adequately segregated and the process has been immediately corrected as appropriate.

Root Cause Analysis - Determine the underlying reason for the variance or noncompliance. Both process root cause (causing the product variance) and Quality System root cause (reason the variance was not detected and escaped the supplier's facility) should be analyzed.

Corrective Action/Plan - Detail the steps necessary to successfully generate corrective action that will permanently correct the situation. Examples of acceptable corrective action:

Improve tooling, fixture, gaging.

Modify and better define manufacturing process.

Revise manufacturing operation sheet to clarify and better define work instructions.

Redefine or modify the product design by changing the specification requirement.

Conduct formal and informal on-the-job training.

Revise measurement system or sampling plan.

Implementation - Implement the steps detailed under "Corrective Action/Plan." Include implementation date for each step.

Effectivity – record date when corrective action is effective. Other information such as Lot/Batch No., Serial Number or other applicable information should also be recorded where shown. The signature of the supplier representative responsible for the corrective action, company name and date should be recorded where shown.

